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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,229

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Ozlem Tureci

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EXAMINER

GODDARD, LAURA B

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1642

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,229	Applicant(s) TURECI ET AL.	
	Examiner LAURA B. GODDARD	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 10, 20-24, 27, 57-60, 74, 83, 95 and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-6, 10, 20-24, 27, 57-60, 74, 83, 95 and 96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2-6, 10, 20-24, 27, 74, 83, drawn to the special technical feature of a pharmaceutical composition comprising an agent with tumor-inhibiting activity, which is selective for cells expressing or abnormally expressing a tumor-associated antigen, said tumor associated antigen having a sequence encoded by a nucleic acid which is selected from (a)-(d) of claim 2.

Additionally, Applicants must elect a single agent or a specified combination of agents comprised in the composition:

- (a) antisense nucleic acid (claim 4, 10iv, 24),**
- (b) antibody (claim 5, 6, 10iii, 20-23),**
- (c) tumor associated antigen (claim 10i, 83),**
- (d) nucleic acid that encodes for a tumor associated antigen (claim 10ii, 74),**
- (e) host cell which expresses a tumor-associated antigen (claim 10v), or**
- (f) isolated complexes between a tumor associated antigen and an HLA molecule (claim 10vi),**

as each agent presents a structurally and functionally *distinct* invention lacking unity, not a species.

Group II, claim(s) 57-60, drawn to the special technical feature of a method of **treating** a disease characterized by expression or abnormal expression of a tumor-associated antigen, which method comprises administering an antibody binding to said tumor-associated antigen or to part thereof and coupled to a **therapeutic agent**.

Group III, claim(s) 57-60, drawn to the special technical feature of a method of **diagnosing** a disease characterized by expression or abnormal expression of a tumor-associated antigen, which method comprises administering an antibody binding to said tumor-associated antigen or to part thereof and coupled to a **diagnostic agent**.

Group IV, claim(s) 57-60, drawn to the special technical feature of a method of **monitoring a disease** characterized by expression or abnormal expression of a tumor-

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associated antigen, which method comprises administering an antibody binding to said tumor-associated antigen or to part thereof and coupled to **a diagnostic agent**.

Group V, claim(s) 95, 96, drawn to the special technical feature of a kit for detecting expression or abnormal expression of a tumor-associated antigen comprising agents for detection of (i)-(iv) of claim 95.

Additionally, Applicants must elect a single agent for detection or a specified combination of agents comprised in the kit that detect:

**(i) nucleic acid which codes for the tumor-associated antigen or part thereof;
(ii) the tumor-associated antigen or part thereof;
(iii) antibodies which bind to the tumor-associated antigen or a part thereof; or
(iv) T-cells which are specific for a complex between the tumor-associated antigen or a part thereof and an MHC molecule, said tumor-associated antigen having a sequence encoded by a nucleic acid selected from (a)-(d) of claim 95, as each agent presents a structurally and functionally *distinct* invention lacking unity, not a species.**

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking Groups I-V appears to be a nucleic acid encoding a tumor-associated antigen or part thereof from a SEQ ID NO listed in claim 2a.

However, said technical feature does not constitute a special technical feature in view of WO 98/37094, Jacobs et al, published August 1998. Jacobs et al teach SEQ ID NO:11 ("DA306_4"; p. 10-12; p. 24-25; p. 80-81), which is a nucleic acid encoding part of the tumor associated antigen encoded by SEQ ID NO:1 of the instant application. SEQ ID NO:11 encodes protein SEQ ID NO:12, and SEQ ID NO:11 has 99.7% local identity to instant SEQ ID NO:1 (see sequence search result #4, Geneseq database, "20090104_201446_us-10-573-229a-1"). Jacobs et al additionally teach neutralizing

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antibodies to the protein encoded by SEQ ID NO:11 that can be used for therapy such as in the case of treating cancer mediated by the protein (p. 60-61).

Therefore, the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept and restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Species election for Groups I-V

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species election below applies to all of: 1) the nucleic acid encoding the tumor-associated antigen expressed by the cell of claim 2; 2) the relevant nucleic acid for the tumor-associated antigens referred to in all of claim 10; 3) the nucleic acid encoding the tumor-associated antigen of claim 57; and 4) the nucleic acid relevant to the tumor-associated antigen referred to in all of claim 95:

(a) a nucleic acid comprising a SEQ ID NO, degenerate of the SEQ ID NO, or hybridizes with the complement of the SEQ ID NO (also ELECT ONE SEQ ID NO listed in claims 2a, 10a, 57a, 95a); OR

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(b) a nucleic acid which hybridizes with the SEQ ID NO, or is complementary to the SEQ ID NO, or is a degenerate (also ELECT ONE SEQ ID NO listed in claims as set forth above).

The following claim(s) are generic: claims 2, 10, 57, 74, 83, and 95.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each SEQ ID NO is a structurally and functionally distinct molecule as well as the tumor-associated antigens that are encoded by each SEQ ID NO and their complements, hence they do not share the same or corresponding technical feature with each other.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642